Incontinence

First-Line Therapy for Stress Incontinence

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Two excellent articles from Europe focus on first-line therapy for patients with stress urinary incontinence. Although many papers have debated the merits of pelvic floor exercise, functional electrical stimulation, and estrogen, few studies have been conducted using strict scientific methodology, which would allow unbiased judgment. The 2 studies selected for review are appropriately designed so that definitive conclusions related to the management of stress incontinence can be made.

Just for fun, please answer the following questions before reading the review.

1. Which of the following is the best first-line treatment for stress urinary incontinence?
   A. Pelvic floor exercise
   B. Functional electrical stimulation
   C. Vaginal cone

2. Can estrogen replacement decrease or prevent stress urinary incontinence?
   A. Yes
   B. No

Single Blind, Randomised Controlled Trial of Pelvic Floor Exercises, Electrical Stimulation, Vaginal Cones, and No Treatment in Management of Genuine Stress Incontinence in Women

Bo K, Talseth T, Holme I.
BMJ. 1999;318:487-493.

What is the best first-line treatment for stress urinary incontinence among pelvic floor exercise, functional electrical stimulation, and vaginal cone? This is a very controversial area of therapy. Many articles in the literature attest that 1 of the 3 is best, but most studies do not compare the modalities in a scientifically valid fashion. If you assemble a urologist, urogynecologist, and physical therapist to discuss the matter, you are likely to get strong and different opinions from each.

This important paper answers the question. In Europe, the management of stress incontinence has gradually shifted from surgical interventions to conservative therapies, including pelvic floor exercise, electrical stimulation, and placement of vaginal cones. While pelvic floor exercise has been proved effective for treating genuine stress incontinence, findings from clinical studies evaluating electrical stimulation and vaginal cones have been inconclusive. Further, no comparative study of the 3 modalities has been conducted. Bo and associates from the Norwegian Centre for Physiotherapy Research, the Norwegian University of Sport and Physical Education, and the National Hospital of Norway, Oslo, conducted a multicenter, single-blind, randomized study to compare the effectiveness of these conservative therapies for genuine stress incontinence. The 107 women enrolled in the trial were randomized to 1 of 4 groups: pelvic floor exercises (n = 25); electrical stimulation (n = 25); vaginal cone (n = 27); or no treatment (control) (n = 30).

The primary outcomes were subjective patient perception of improvement and results of a pad test with standardized bladder volume. Secondary outcomes included the number of involuntary leakage episodes over 3 days; results from the 24-hour pad test; leakage index score, obtained from patient reports of frequency of urinary leakage during such activities as coughing, sneezing, laughing, and physical exertion before and after treatment; and social activity index (the level of patient participation in social activities).

There have been studies of conservative therapy for stress incontinence in which most patients reported some improvement with noninvasive therapy. In the trial reported by Bo and associates, all patients in treatment groups experienced improvement, whereas patients in the control group generally did not. Only women in the pelvic floor exercise group achieved significant improvement, compared with the those in the control group ($P < .01$). Improvement in the pelvic floor exercise group correlated with increased strength of pelvic floor muscles ($P = .03$). No change in pelvic muscle strength was observed between women in the electrical stimulation group or those in the vaginal cone group.

Women in the pelvic floor exercise group also experienced improvement in the pad test with standardized bladder volume ($P = .02$), reduced episodes of leakage over 3 days ($P < .01$), and improvement in both the social activity index ($P < .01$) and the leakage index ($P < .01$). Pelvic floor exercises also resulted in objective cure (2 g or less of leakage in the pad test with standardized bladder volume) in significantly more women (n = 11; $P < .02$) than did the other therapies (7, electrical stimulation; 2, vaginal cone; 2, con-

trol). Similarly, significantly more women in the pelvic exercise group reported subjective cure (n = 14, $P < .001$), compared with 3 in the electrical stimulation group, 2 in the vaginal cone group, and 1 in the control group.

None of the women in the pelvic floor exercise group experienced any adverse effects of therapy. Two women who received electrical stimulation reported tenderness and bleeding or discomfort, while 8 indicated they had motivation problems and difficulties using the stimulator. Fourteen patients in the vaginal cone group also had difficulties with motivation and/or the device; additionally, 1 experienced abdominal pain, vaginitis developed in 2; and 1 reported bleeding.

What is the take-home message in this article? It appears that the best first-line treatment for patients with stress urinary incontinence among pelvic floor exercise, functional electrical stimulation, and vaginal cone is also the least expensive: pelvic floor exercise.

The Effect of Oestrogen Supplementation on Post-Menopausal Urinary Stress Incontinence: A Double-Blind Placebo-Controlled Trial

Jackson S, Shepherd A, Brookes S, Abrams P.
Br J Obstet Gynaecol. 1999;106:711-718.

This study addresses the question of whether estrogen replacement can decrease or prevent stress urinary incontinence. The rationale is certainly logical. It is well known that there is an increasing prevalence of urinary incontinence with age and menopause. Therefore, it is logical to postulate that hormone replacement therapy (HRT) may have a therapeutic role in postmenopausal incontinence. The first report of estrogen replacement was published more than 50 years ago and, since then, several hundred papers on this topic have appeared in the literature. The majority of these reported studies have been small and uncontrolled; most have suggested that HRT is beneficial. A placebo-controlled study is essential to establish the treatment-related advantage of estrogen replacement.

The purpose of this study by Jackson and associates from the Southmead Hospital, Bristol, UK, was to investigate the effect of HRT on postmenopausal urinary stress incontinence. This double-blind, placebo-controlled, randomized trial was conducted at a teaching hospital associated with Bristol University. The population comprised postmenopausal women with genuine stress incontinence who were not receiving HRT. The women were randomized to 6 months of therapy with estradiol valerate, 2 mg daily, or to placebo. Assessment, both before treatment and on study completion, was done with the SF-36 health status questionnaire, the Bristol Female Lower Urinary Tract Symptoms questionnaire, a 1-week urinary diary, 1-hour perineal pad test, cystometry, and urethral profilometry.

Sixty-seven women were randomized to receive estrogen or placebo. Mean age was 63 years. Five women did not have repeat assessment; 3 of the 5 were receiving estrogen. Six women receiving estradiol had breakthrough bleeding during the 6 months; they received additional monthly progestogen. There was no significant effect of estrogen over placebo for any subjective or objective clinical outcome.

This trial is one of the largest controlled studies of the effect of estrogen replacement on stress incontinence; it also has the longest duration of treatment. After 6 months of estrogen therapy, no improvement in postmenopausal stress incontinence was demonstrated. Apart from a slight increase in functional urethral length, HRT has only minimal effect on subjective or objective lower urinary tract function.

These results are consistent with another well-done controlled trial evaluating the effect of estrogen replacement on stress incontinence.[1] Eighty-three postmenopausal women, 70% of whom had either genuine or mixed incontinence, were treated with either 0.625 mg conjugated equine estrogen or placebo. While the study was reported as being double-blind, the women treated with estrogen received medroxyprogesterone acetate for 10 days each month and would therefore have experienced withdrawal bleeding if they had not had hysterectomies. The treatment lasted 3 months. During that time, no significant advantage over placebo was found concerning the number of incontinence episodes, objective fluid loss, frequency of micturition, quality-of-life measures, or subjective improvement.

What is the take-home message? The next time a postmenopausal woman with incontinence or a medical colleague asks you if estrogens improve urinary incontinence, the answer is, unfortunately, no.

Reference

1. Fantl JA, Bump RC, Robinson D, et al. Efficacy of estrogen supplementation in the treatment of urinary incontinence. *Obstet Gynecol.* 1996;88:745-749.

Based on the studies reviewed, the correct answers to the 2 questions are 1: A. Pelvic floor exercise; 2. B. No.